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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,193	07/10/2006	Gerd Dahms	4266-0110PUS1	7394

23413 7590 11/12/2010

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EXAMINER	
SOROUSH, ALI	
ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
11/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/550,193	DAHMS ET AL.	
	Examiner	Art Unit	
	ALI SOROUSH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt

Applicants response filed on 07/26/2010 to the Office Action mailed on 03/29/2010 is acknowledged.

Claim Status

Claims 16-31are pending.

Claims 1-15 are cancelled.

Claims 16-31 have been examined.

Claims 16-31 are rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16 and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 and 20 of copending Application No. 2007/0105746 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because Application No. 2007/0105746 A1 claims a composition and method of preparing a composition for "targeted release of fragrances and/or aromas in the form of solid lipid nanoparticles (SLN) dispersion in which lipid-based nanoparticles are present which are stabilized by an emulsifier monoloayer, one or more membrane layers or other auxiliaries, the fragrances and/or aromas being included in the nanoparticles and/or in the emulsifier monolayer or the membrane layers, preparable by a) mixing the fragrance and/or aroma with the lipid-based active ingredient carrier and at least one emulsifier, which leads, in stage b), to the formation of a lyotropic liquid-crystalline mixed phase, at temperature above the melting or softening point of the active ingredient carrier, to form a phase B, where lipids and emulsifiers are used in a weight ratio of from 50:1 to 2:1, b) mechanical mixing of the phase B with an aqueous phase or polyol phase A which can comprise and emulsifier, at a temperature above the melting or softening point of the active ingredient carrier, where the weight of phase B to phase A is 1:5 to 5:1, without high-pressure homogenization, to form a lyotropic liquid-crystalline mixed phase, c) dilution of the mixed phase with an aqueous phase or polyol phase which can comprise an emulsifier, at a temperature of the aqueous phase or polyol phase which is below the melting or softening point of the active ingredient carrier, with stirring and without high-

pressure homogenization, to a desired end concentration of the dispersion." (See claims 14 and 20).

However, Application No. 2007/0105746 A1 does not claim any particular particle average diameter. The instantly claims particle diameter range, 10 to 10, 000nm, would have been obvious to one of ordinary skill in the art at the time of the instant invention. One would have been motivated to arrive at the instant particle diameter range through routine optimization in order to provide a composition that is clear. (See paragraph 0044). For the foregoing reasons, instant claims 16 and 22 are obvious over claims 14 and 20 of Application No. 2007/0105746 A1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Applicant's Arguments

Applicant argues that they will defer responding to the provisional rejection until the claims in the reference application are allowed. Therefore, the instant rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 16 and 19-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanlerberghe et al. (US Patent 5985255, Published 11/16/1999).

The claims are directed to a method of producing an aqueous vehicle dispersion with particles in the range of 10 to 10000nm comprising: a) making a mixture of wax, emulsifier, and an active agent at above the melting temperature of the wax, b) combining the mixture with an aqueous phase in 1:5 to 5:1 ratio of the total percent of the dispersion, and c) diluting the mixture with an aqueous solution to a desired final

concentration. The claims are further directed to a oil phase can be mixed with the aqueous vehicle dispersion.

Vanlerberghe et al. show a method for preparing a microdispersion of solid particles in a single phase aqueous vehicle comprising mixing wax, emulsifier, optionally up to 30% active ingredient, optionally an oil and melting the mixture and progressively adding heated water to form a microemulsion. (column 11, Lines 14-47). The microemulsion is then cooled to form a microdispersion having particle sizes of less than 500nm. (column 11, Lines 48-51). The microemulsion can be further diluted with water. (column 5, Lines 45-55). In a preferred embodiment, a mixture of 10% carnaubu wax, 3.79% CTA bromide (cationic emulsifier) and 3% parsol MCX (sunscreen agent) are combined with 83.21% water, which is a ratio of aqueous phase to wax phase of approximately 5:1. (column 7, Lines 50-67). In a preferred embodiment the dispersion comprises 10% carnauba wax, 3.79% CTA bromide, an adjustable amount of active agent, and an adjustable amount of water such that the total composition equals 100%. (column 7, Lines 50-60).

Vanlerberghe et al. does not show a microdispersion that has been diluted.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the microdispersion of Vanlerberghe et al. by diluting with water, since Vanlerberghe et al. teach that diluting the composition would result in adjusting the concentration of wax present in the final formulation for application. With regard to the instantly claimed ratio of 1:2 phase A to phase B, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to arrive at

such a ratio through routine optimization. One would have been motivated to do so in order to change the concentration of active agent being administered. Therefore, if one wanted to adjust the amount of active being delivered then subsequently the amount of water (aqueous phase) would also be similarly adjusted.

2. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanlerberghe et al. (US Patent 5985255, Published 11/16/1999) as applied to claims 16 and 19-31 above, and further in view of Dahms (US Patent 5747012, Published 05/05/1998).

The claims are further directed to mixing of the two phases by a household kitchen mixer with a peripheral speed in the range from 1 to 20 m/s.

The teachings of Vanlerberghe et al. are discussed above.

Vanlerberghe et al. lacks a showing wherein the mixing is done by a household kitchen mixer.

Dahms teach mixing an aqueous phase with an oil/wax phase with a high speed stirring mixer, i.e. Braun mixer type 4189. (column 7, Lines 30-67 and column 8, Lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the invention of Vanlerberghe et al. by using the mixer of Dahms in order to mix the two phases of in taught by Vanlerberghe et al., since Vanlerberghe et al. is silent as to the device used in mixing and Dahms teaches the mixer being for the same purpose. With regard to the peripheral speed of the mixer,

since the mixer disclosed by Applicant in the specification and the mixer taught by Dahms are the same it would be expected that the peripheral speeds would be identical.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALI SOROUSH whose telephone number is (571)272-9925. The examiner can normally be reached on M-F (9am-6pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on (571)272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 1617

/KARLHEINZ R SKOWRONEK/
Primary Examiner, Art Unit 1631

October 9, 2010